CLAIMS

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1. A method of preserving biologically-active material comprising mixing an aqueous suspension of the biologically-active material with a sterile aqueous solution of chitosan or a non-toxic salt thereof to form a coacervate of the biologically-active material and chitosan or non-toxic salt thereof, adding to the coacervate a sterile aqueous solution of trehalose, subjecting the sterile mixture of coacervate and trehalose to drying at a pressure less than atmospheric and at a temperature, initially no greater than 37°C, which is subsequently controlled not to fall to 0°C or below to form a glassy porous matrix comprising metastable glassy trehalose containing, within the matrix, desiccated biologically-active material and chitosan or non-toxic salt thereof.

2. A method according to claim 1, wherein the biologically-active material is selected from viruses, bacteria, tertiary structured biologically-active protein and nucleic acid.

3. A method according to claim 2, wherein the biologically-active material is at least one virus selected from Rinderpest virus, Peste de Petit Ruminants virus, Measles, Mumps, Rubella, Yellow Fever, Polio and Newcastle Disease Virus.

4. A method according to claim 2, wherein the biologically-active material is Contagious Bovine Pleuropneumonia (CBPP) mycoplasma.

5. A method according to any one of claims 1 to 4, wherein the sterile aqueous solution of chitosan or non-toxic salt thereof has a chitosan concentration of 0.01% w/v.

6. A method according to claim 5, wherein the sterile aqueous chitosan solution and the aqueous suspension of biologically-active material are mixed at a volume ratio of 1:1 at pH 7.4.

7. A method according to any one of claims 1 to 6, wherein the coacervate of biologically-active material and chitosan is subjected to vortex mixing.

8. A method according to any one of claims 1 to 7, wherein the coacervate of biologically-active material and chitosan is mixed with a sterile aqueous trehalose solution having a trehalose concentration in the range of from 0.20 to 20% w/v.

9. A method according to claim 8, wherein the sterile aqueous solution of trehalose has a trehalose concentration in the range of from 2.5 to 8% w/v.

10. A method according to claim 9 wherein the sterile aqueous solution of trehalose has a trehalose concentration of about 5% w/v.

11. A method according to any one of claims 1 to 10, wherein the mixture of coacervate and trehalose is subjected to drying for 30 to 60 minutes, at a pressure of less than atmospheric and at a temperature initially no greater than 37°C, and which is controlled not to fall to 0°C or below and which is finally no greater than 40°C to form a glassy porous matrix comprising glassy trehalose having a residual moisture content not greater than 10% and containing, within the matrix, desiccated biologically-active material and chitosan or non-toxic salt thereof.

12. A method according to any one of claims 1 to 11, wherein the drying stage is carried out at a pressure of not greater than 800 mbar.

13. A method according to any one of claims 1 to 12, wherein the resulting trehalose matrix containing desiccated biologically-active material and chitosan or non-toxic salt thereof is subjected to a secondary drying procedure for 10 to 30 hours of a pressure not greater than 0.1 mbar and at a temperature which finally is in the range of from 40 to 45°C to form a trehalose matrix having a residual moisture content of not greater than 2% containing, within the matrix, desiccated biologically-active material and chitosan or non-toxic salt thereof.

14. A method according to claim 12, wherein secondary drying is carried out for 20 to 30 hours.

15. A method according to claim 13, wherein secondary drying is carried out for 15 to 17 hours at a temperature of about 37°C and the temperature is, thereafter, raised gradually over the remaining secondary drying time to a final temperature in the range of from 40 to 45°C.

16. A method according to any on of the claims 12 to 14, wherein the residual moisture content at the end of the secondary drying step is 1.0% or lower.

17. A method of making a vaccine comprising preserving a biologically-active material according to the method of claims 1 to 15 and rehydrating the glassy product obtained thereby in an appropriate aqueous medium.

18. A method according to claim 16, wherein the vaccine is for oral or intranasal use.

19. A method according to claim 17, wherein the vaccine is a Measles, Mumps, Rubella (MMR) vaccine.

20. A rehydratable composition comprising trehalose in the form of a metastable glass matrix containing, within the matrix, desiccated biologically-active material and chitosan or a non-toxic salt thereof.

21. A rehydratable composition according to claim 19 which has a residual moisture content of not greater than 2%.

22. A reydratable composition according to claim 20 which has a residual moisture content of not greater than 1%.

23. A rehydratable composition according to any one of claims 19 to 21, useful on rehydration for making a vaccine.

24. A rehydratable composition according to nay one of claims 19 to 22, wherein the biologically-active material is selected from viruses, bacteria, tertiary structured biologically-active proteins and nucleic acids.

25. A rehydratable composition according to claim 23, wherein the biologically-active material is at least one virus selected from Rinderpest Virus, Peste de Petit Ruminants Virus, Measles, Mumps, Rubella, Yellow Fever, Polio Myelitis and Newcastle Disease Virus.

26. A rehydratable composition according to claim 23, wherein the biologically-active material is Contagious Bovine Pleuropneumonia (CBPP) mycoplasma.

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